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EXAMINER

CHEN, SHIN LIN

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 05/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,408

Applicant(s)

Tsvetkova et al.

Examiner

Shin-Lin Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 21, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-73 is/are pending in the application.
- 4a) Of the above, claim(s) 33-52 and 64-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

1. Applicant's election without traverse of group II, claims 53-63, in Paper No. 7 is acknowledged.
2. Claims 33-52 and 64-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 7.

Applicants' preliminary amendment filed 8-23-01 has been entered. Claims 1-32 have been canceled. Claims 33-73 have been added. Claims 33-73 are pending and claims 53-63 are under consideration.

Claim Objections

3. Claim 54 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Uptaking external trehalose via fluid phase endocytosis from the trehalose solution is part of the process step in loading trehalose into the platelets of the process of claim 53. Therefore, claim 54 fails to further limit the subject matter of claim 53.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 58 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "fixative" in claims 58 and 59 is vague and renders the claims indefinite. The term "fixative" means "something that fixes or sets" or "a substance used to fix living tissue". The meaning of the term "fixative" is very broad and vague. It is unclear as to the metes and bounds of what would be considered "fixative". The specification fails to specifically define the term "fixative".

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 56-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 58 and 59 read on loading platelets that do not include a fixative with trehalose.

"Loading platelets that do not include a fixative with terhalose" is considered new matter because

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the specification fails to provide sufficient description for loading platelets that do not include a fixative.

Claims 56, 57 and 60-63 read on a second phase transition temperature range that is greater than about 25°C, greater than about 25°C to less than 40°C, or from about 30°C to less than 40°C. A second phase transition temperature range that is greater than about 25°C, greater than about 25°C to less than 40°C, or from about 30°C to less than 40°C is considered new matter. The specification describes a second phase transition temperature range between 30°C and 37°C (see specification, pages 6, 9), and loading trehalose to platelets at a temperature greater than about 25°C to less than 40°C. However, the specification fails to provide sufficient description for a second phase transition temperature range that is greater than about 25°C, greater than about 25°C to less than 40°C, or from about 30°C to less than 40°C. Thus, claims 56, 57 and 60-63 read on subject matter that is considered new matter.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 53, 55, 58 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by

Beattie et al., 1998 (WO 98/14058).

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Claims 53, 55, 58 and 59 are directed a process for increasing the loading efficiency of trehalose into platelets, such as human platelets, comprising disposing the platelets into a trehalose solution and heating the trehalose solution to a second phase transition temperature range to increase the loading efficiency of the trehalose into the platelets. Claims 58 and 59 specify the platelets do not include a fixative.

Beattie teaches using preservation-enhancing amount of the combination of trehalose and DMSO as cryoprotectant for islets and islet-like cell clusters as well as human platelets, and teaches that trehalose can be incorporated into eukaryotic cells in the absence of DMSO by suspending the cells in trehalose solution and cooling or warming the suspension through the thermotropic phase transition (e.g., abstract, p. 5, 9, 21). The human platelets do not include a fixative. Thus, claims 53, 55, 58 and 59 are anticipated by Beattie.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 53-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beattie et al., 1998 (WO 98/14058) in view of Diniz-Mendes et al., 1999, (Biotechnology and Bioengineering, Vol. 65, No. 5, p. 572-578).

Claims 53-57 are directed a process for increasing the loading efficiency of trehalose into platelets, such as human platelets, comprising disposing the platelets into a trehalose solution and heating the trehalose solution to a second phase transition temperature range to increase the loading efficiency of the trehalose into the platelets. Claim 53 specifies the uptake of external trehalose is via fluid phase endocytosis from the trehalose solution. Claims 56 and 57 specify the second phase transition temperature range is greater than about 25°C.

Beattie teaches using preservation-enhancing amount of the combination of trehalose and DMSO as cryoprotectant for islets and islet-like cell clusters as well as human platelets, and teaches that trehalose can be incorporated into eukaryotic cells in the absence of DMSO by suspending the cells in trehalose solution and cooling or warming the suspension through the thermotropic phase transition (e.g., abstract, p. 5, 9, 21).

Beattie does not teach uptake of external trehalose via fluid phase endocytosis from the trehalose solution and the second phase transition temperature range is greater than about 25°C.

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Diniz-Mendes teaches trehalose is a natural cryoprotectant for preserving human red blood cells, bacterial cells and yeast cells during low-temperature treatment. Diniz-Mendes further teaches that pre-exposure of cells to 40°C for 60 min and addition of trehalose can enhance survival rate of cells in freezing and freeze-drying treatments of cells, and the heat treatment can increase the accumulation of intracellular trehalose of cells treated while intracellular trehalose remain unaltered during cold shock exposure (e.g. abstract, introduction).

It would have been obvious for one of ordinary skill at the time of the invention to heat the cells, such as human platelets, at 40°C for 60 min as taught by Diniz-Mendes because trehalose is a natural cryoprotectant and this heat exposure of cells to trehalose can increase the intracellular amount of trehalose in said cells. Since Diniz-Mendes teaches heating cells in a solution containing trehalose, and uptaking external trehalose via fluid phase endocytosis from the trehalose solution is part of the process step in heating the trehalose solution to a second phase transition temperature range, it would have been obvious for one of ordinary skill at the time of the invention that the heating step taught by Diniz-Mendes would result in uptaking external trehalose via fluid phase endocytosis into cells.

One ordinary skill in the art at the time the invention was made would have been motivated to do so in order to enhance survival rate of cells in freezing and freeze-drying treatments of cells as taught by Diniz-Mendes with reasonable expectation of success.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

A handwritten signature in cursive script, appearing to read 'S. Chen'.